

## REMARKS

As an initial matter, Applicants wish to thank the Examiner for withdrawing previous rejections.

Claims 24 and 26-33 are pending in the application and are presented for examination. No claim has been amended or cancelled in this Response.

### **I. Rejection Under 35 U.S.C. § 112, Second Paragraph**

Claims 32 and 33 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. In particular, the Office Action alleges the terms “lower respiratory tract infection” and “upper respiratory tract infection” are unclear. Specifically, the Office Action alleges that the terms are relative, and that it is not clear where the cutoff between the “upper” and the “lower” respiratory tract is located (*see*, page 2 of the Office Action). Applicants respectfully traverse the rejection.

“Upper respiratory tract” and “lower respiratory tract” are defined areas of the respiratory tract, and are terms commonly used in the art. One of ordinary skill in the art knows that the respiratory tract is divided into two main parts: the upper respiratory tract and the lower respiratory tract. The upper respiratory tract consists of the nose, the nasal cavity and the pharynx. The lower tract consists of the larynx, the trachea, the bronchi and the lungs. The pharynx is a muscular tube serving to connect the nasal cavity and the mouth with the lower respiratory tract and the esophagus. The larynx, also known as voice box, lies between the pharynx and the trachea. Thus, the points below the pharynx and above the larynx is the cutoff between the “upper” and the “lower” respiratory tract. As such, the terms “lower respiratory tract infection” and “upper respiratory tract infection” refer to infections found in one of two clearly defined regions of the respiratory tract. Infections of the larynx, the trachea, the bronchi or the lungs are lower respiratory tract infections. Infections of the nose, the nasal cavity, or the pharynx are upper respiratory tract infections. Examples of upper respiratory tract infections

include, for example, acute sinusitis and pharyngitis (*see*, page 16, Table I of the specification). Lower respiratory tract infections include, for example, pneumonia and bronchitis. Since the terms “lower respiratory tract infection” and “upper respiratory tract infection” are commonly used in the art and are not indefinite, Applicants respectfully request that the rejection be withdrawn.

## II. Rejection Under 35 U.S.C. § 102(e)

Claims 24, 26, 27, 29 and 31 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 5,971,937, issued to Ekstrom (hereinafter the “Ekstrom patent”). Applicants respectfully traverse the rejection as Ekstrom does not disclose all the elements set forth in the present invention.

It is axiomatic that claims are anticipated if, and only if, **each and every element** as set forth in the claim is found in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051 (Fed. Cir. 1989). Furthermore, “[t]he **identical invention must be shown in as complete detail as is contained in the...claim.**” (emphasis added) *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913 (Fed. Cir. 1989). See also, *PPG Industries Inc. v. Guardian Industries Corp.*, 7 USPQ2d 1618, 1624 (Fed. Cir. 1996) (“To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.”)

The Ekstrom patent discusses a method and apparatus for measuring a blood alcohol concentration. To achieve a correct alcohol concentration measurement, the Ekstrom patent discusses measuring both alcohol concentration and carbon dioxide concentration of the subject’s exhalation air. See, column 4, lines 18-26. As stated in the Ekstrom patent and evidenced in accompanying Figures (See, for example, column 10, lines 14-45, and Figures 1 and 2), as the exhalation air stream 9 that is to be analyzed flows through the channel 10, infrared radiation is irradiated through the channel 10 some of the infrared radiation is absorbed by gases that are present in the channel 10. The

resulting infrared radiation is then detected and analyzed via one or more sensors 3a and 3b. As clearly indicated in Figures 1 and 2, the exhalation air stream 9 does **not** come in contact with the sensors. In fact, the exhalation air stream 9 remains within the confines of channel 10 and **does not** touch the sensor directly. The exhalation air stream 9 is analyzed by transmitting infrared radiation through the channel 10 and determining the amount of infrared radiation absorption by alcohol and/or carbon dioxide that are present in the exhalation air. The optical sensors discussed in the Ekstrom patent determine the amount of alcohol and carbon dioxide concentration by analyzing infrared absorption by the exhalation air. Thus, in the apparatus discussed in the Ekstrom patent, it is ultimately infrared radiation that comes in “contact” with the sensors, not the exhalation air stream.

Moreover, the Ekstrom patent does not compare the profile of the first breath sample with the profile of the second breath sample. The Ekstrom patent merely discusses quantifying only the carbon dioxide and alcohol contents of the subject’s breath. The quantitative analysis in the Ekstrom patent involves comparing the measured alcohol and carbon dioxide values with a predetermined value stored in the memory. See the Abstract. In particular, the Ekstrom patent discusses comparing the carbon dioxide value to ensure that it is above the predetermined minimum value and below the predetermined maximum value. See, for example, Col. 5, lines 32-53.

In contrast, methods of the present invention comprise “**contacting** an array of sensors with a first sample of...breath...[and] **contacting** an array of sensors with a second sample of...breath....” (emphasis added) See claim 24. The term “contact” is defined as “the touching of two objects or surfaces.” See *Webster’s II New College Dictionary*, Houghton Mifflin Co., 2001, p. 242, which is included herewith as Exhibit A for the Examiner’s convenience. Thus, methods of the present invention require the subject’s exhalation air (i.e., breath) to touch the sensor directly. In addition, methods of the present invention involve storing the analysis results of the first sample in a **computer-readable format**. Furthermore, methods of the present invention comprise comparing the results of the second breath sample with the stored results of the analysis

of the first breath sample. Moreover, there is no minimum or maximum value for any analytes in methods of the present invention.

Since methods discussed in the Ekstrom patent require comparison of one of the analytes (i.e., carbon dioxide) to be within a predetermined range and does not teach (1) contacting the subject's breath with the sensor or (2) storing the analysis results of a first breath sample in a computer-readable format, the Ekstrom patent does **not** anticipate the present invention. Therefore, Applicants respectfully request that the rejection under 35 U.S.C. § 102(e) be withdrawn.

### III. Rejection Under 35 U.S.C. § 103(a)

#### Rejection of Claim 30

Claim 30 has been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Ekstrom in view of U.S. Patent No. 5,787,885, issued to Lemelson (hereinafter the "Lemelson patent"). In particular, the Office Action alleges that the Ekstrom patent teaches every element of claim 30 except for a neural net trained against known analytes (see, page 5 of the Office Action). However, the Office Action alleges that it would have been obvious to one of skill in the art to combine the neural net discussed in the Lemelson patent with the teachings of the Ekstrom patent. Furthermore, the Office Action alleges that the addition of neural net algorithms to perform diagnostic algorithms is suggested by Lemelson. Applicants respectfully traverse the rejection because (1) there is no motivation or suggestion in either the Ekstrom or the Lemelson patent to combine the respective teachings and (2) more significantly, the Lemelson patent does not make-up the deficiencies in the Ekstrom patent.

As the Examiner is well aware, claims cannot be found obvious unless the prior art **teaches or suggests** making the claimed product. *See In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991) (The teaching or suggestion to make the claimed combination or modification and the reasonable expectation of success must **both be found** in the prior art), *In re Mills*, 16 USPQ2d 1430 (Fed. Cir., 1990) (The mere fact that references can be

combined or modified does **not** render the resultant combination or modification obvious **unless** the prior art also **suggests the desirability** of the combination or modification.) There must be something in the prior art that would have motivated persons of ordinary skill to make the combination. *In re Stencel*, 4 USPQ2d 1071, 1073 (Fed. Cir. 1987), *accord*, *Ex parte Marinaccio*, 10 USPQ2d 1716 (Pat. Off. Bd. App. 1989) (combining references is improper absent some teaching, suggestion, or motivation for the combination in the prior art), *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990) (The mere fact that references can be combined or modified does **not** render the resultant combination or modification obvious **unless** the prior art also **suggests the desirability** of the combination or modification. Thus, although a prior art device “may be capable of being modified to run the way the apparatus is claimed, there **must be a suggestion or motivation in the reference** to do so”). In this respect, the following statement by the Patent Office Board of Appeals is noteworthy:

Our reviewing courts have often advised the Patent and Trademark Office that it can satisfy the burden of establishing a *prima facie* case of obviousness only by showing some objective teaching in either the prior art, or knowledge generally available to one of ordinary skill in the art, that “would lead” that individual “to combine the relevant teachings of the references.” ... Accordingly, an examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant’s invention without also providing evidence of the motivating force that would **impel** one skilled in the art to do what the patent applicant has done.

*In re Levengood*, 28 U.S.P.Q.2d 1300, 1302 (Pat. Off. Bd. App. 1993) (citations omitted; emphasis added). Significantly, the Office Action identifies no “motivating force” that would “impel” persons of ordinary skill to combine the respective teachings of the cited references in a manner that would produce the claimed inventions.

The apparatus discussed in the Lemelson patent is directed to collecting a breath sample. See the Abstract, and Col. 3, lines 25-33. The collected breath sample is then analyzed, thus requiring at least two separate steps. However, the apparatus

discussed in the Ekstrom patent does not collect a breath sample. It analyzes the breath directly as it is being exhaled into the channel 10 in a single step. See, Col. 10, lines 14-45 of the Ekstrom patent. Since the apparatus discussed in the Ekstrom patent is directed to quickly and accurately measuring the alcohol content in the subject's breath, one skilled in the art will recognize that the apparatus requires a direct measurement of the subject's breath in a single step rather than collecting the breath sample and then measuring the collected sample in a two-step process. One skilled in the art will recognize that collecting the breath sample prior to measuring its alcohol content increases the possibility of error, for example by diffusion of gas, thereby reducing the accuracy of the measurement. This is especially true for a quantitative analysis, since the diffusion rate of each gas is different. Thus, one skilled in the art would not be motivated to combine the teachings of the Ekstrom patent and the Lemelson patent. In fact, since collecting a breath sample in a separate sample collector device prior to its analysis increases the possibility of errors, one skilled in the art would be **discouraged** from combining the teachings of the Ekstrom patent and the Lemelson patent.

More significantly, even if *arguendo* the teachings of the Ekstrom patent and the Lemelson patent are combined (Applicants maintain that there is no motivation to do so), the resulting method is different from methods of the present invention. Claim 30 is dependent upon independent claim 24 and therefore encompasses all of the features of claim 24. According to claim 24, the subject's breaths are contacted with the sensor array and the analysis results of the first breath sample are stored in a computer-readable format. This stored analysis results are then compared with the profiles of the second breath sample.

As discussed above, the Ekstrom patent does **not** teach or suggest contacting the exhalation air with the sensors or storing the analysis results in a computer-readable format. In addition, methods discussed in the Ekstrom patent require comparison of the amount of carbon dioxide in the exhalation air with predetermined values.

The Lemelson patent discusses a device and method for analyzing body fluids that may be used for testing the breath of humans (*see*, column 3, lines 25-45 of Lemelson). The Lemelson patent does **not** teach or suggest storing the analysis results of a first breath sample in a computer-readable format and comparing this analysis results with a second breath sample. In fact, the Lemelson patent discusses simply comparing the breath sample analysis “with a set point” which can be “determined by a simple calculation or table look-up using data inputted by the user....” (Col. 9, lines 19-21). Thus, combination of the teachings of the Ekstrom patent and the Lemelson patent would result in analyzing the breath sample to a set data point that is calculated or is inputted by the operator.

In contrast, methods of the present invention comprise comparing the analysis results of the first breath sample with the second breath sample. Accordingly, Applicants respectfully request that the rejection of claim 30 under 35 U.S.C. § 103(a) based on the Ekstrom patent in view of the Lemelson patent be withdrawn.

Rejection of Claims 24, 28 and 31-33

Claims 24, 28 and 31-33 have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 6,057,162, issued to Rounbehler et al., (hereinafter the “Rounbehler et al. patent”) in view of the Ekstrom patent. In particular, the Office Action alleges that it would have been obvious to one of skill in the art to combine multiple reading and comparing steps taught by the Ekstrom patent with the method for disease diagnosis by vapor sample analysis taught by the Rounbehler et al. patent in order to arrive at the present invention. Applicants respectfully traverse the rejection.

It is submitted that there is no teaching or motivation to combine the teachings of the Ekstrom patent and the Rounbehler et al. patent. Moreover, Applicants submit that a *prima facie* case of obviousness has not been established because the prior art references, even if combined, do not teach or suggest all the claim limitations.

As discussed in Section II above, methods of the present invention comprise “**contacting** an array of sensors with a first sample of...breath...[and] **contacting** an array of sensors with a second sample of...breath...” (emphasis added). Thus, methods of the present invention require the subject’s exhalation air (i.e., breath) to touch the sensor directly. In addition, methods of the present invention involve storing the analysis results of the first sample in a **computer-readable format**. Furthermore, methods of the present invention comprise comparing the results of the second breath sample with the stored results of the analysis of the first breath sample. Moreover, there is no minimum or maximum value for any analytes in methods of the present invention.

The Office Action acknowledges that the Rounbehler et al. patent does not teach multiple sample readings that are compared to each other. Since no multiple sample readings are conducted in methods discussed in the Rounbehler et al. patent, there is no need to store any analysis results in methods discussed in the Rounbehler et al. patent. It follows then the Rounbehler et al. patent does not teach or suggest the storage of analysis results of the first breath in a computer-readable format. Therefore, the Rounbehler et al. patent does **not** make up the deficiencies in the Ekstrom patent.

The detector unit of the Rounbehler et al. patent includes a gas chromatograph system, a conversion chamber and a chemiluminescence detector. See Col. 3, lines 43-47. The sample breath is separated and subjected to a catalytic reaction. The products of the catalytic reaction are then analyzed via the chemiluminescence detector. See Col. 7, lines 7-20. Thus, the breath sample is analyzed indirectly in the Rounbehler et al. patent by first converting the breath sample by a catalytic reaction. Moreover, chemiluminescence analysis involves measuring the light emitted by the converted breath sample; therefore, the analysis method discussed in the Rounbehler et al. patent does not require a direct contact between the converted breath sample and the sensor. Thus, even if the teachings of the Rounbehler et al. patent is combined with the teachings of the Ekstrom patent (Applicants maintain that there is no motivation or teaching to do so), the resulting combination does not lead to the present invention. For



example, combination of the teachings of the Rounbehler et al. patent and the Ekstrom patent results in subjecting the breath sample to a catalytic reaction and analyzing the converted breath sample without the need for a contact between the converted breath sample and the sensor.

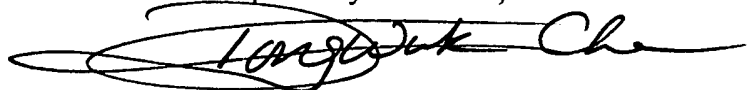
In contrast, methods of the present invention comprise analyzing the breath sample directly without first converting the breath sample via a catalytic reaction. In addition, methods of the present invention require a contact between the breath sample and the sensor array. Accordingly, Applicants respectfully request that the rejection of claims 24, 28 and 31-33 under 35 U.S.C. § 103(a) over the Rounbehler et al. patent in view of the Ekstrom patent be withdrawn.

### CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Don D. Cha", is written over a horizontal line.

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